274 mm x 218mm

Insight | RF

Rapid Immunochromatographic assay for the detection of Rheumatoid factors in human serum

DEVICE

INTENDED USE

INSIGHT-RF is a rapid, self-performing, immunochromatograhic assay for the detection of Rheumatoid factors in human serum.

SUMMARY

Sometimes autoantibodies are produced by the human body against self antigens. The precise role that this aberrant immunity plays in the pathogenesis of certain rheumatic diseases is unknown. However the presence of these autoantibodies serves as credible marker of the disease.

In rheumatoid arthritis, diagnostically useful autoantibodies termed as "Rheumatoid factors" (RF) can be detected which are immunoglobulins of the class IgM, IgG, IgA and IgE. Practically, IgM class RF with specificity to human IgG (Fc) is the most useful prognostic marker of RA. The clinical significance of RF determinations consists in differentiation between rheumatoid arthritis, in which RF of modified IgM class have been demonstrated in the serum of approximately 80% of the cases examined and rheumatic fever, in which RF are almost always absent.

INSIGHT-RF detects the presence of Rheumatoid factors in human serum, qualitatively, at concentrations as low as 10 IU/ml.

PRINCIPLE

INSIGHT-RF is based on the principle of agglutination of antibodies/antisera with respective antigen in immunochromatography format along with use of nano gold particles as agglutination revealing agent. The conjugate pad is impregnated with two components; agglutinating sera for human IgM conjugated to colloidal gold and Rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the agglutinating sera forhuman IgM colloidal gold conjugate complexes with the RF in the test specimen and travels on the membrane due to capillary action along with the rabbit globulin colloidal gold conjugate. This complex moves further on the membrane to the test region where it is immobilized by Fc fraction of human IgG coated on the membrane, leading to formation of pink/purple coloured band. The absence of this band in the test region indicates a negative result. The rabbit globulin colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the agglutinating sera for rabbitglobulin coated on the membrane at the control region (C) forming a pink / purple coloured band. This control band acts as a procedural control and serves to validate the results.

REAGENTS AND MATERIALS SUPPLIED

A. Each INSIGHT-RF kit contains individual pouches each containing a
   1. Membrane test assembly impregnated with colloidal gold conjugated to agglutinating sera for human IgM and the rabbit globulin, Fc fraction of human IgG and Agglutinating sera for rabbit globulin at the respective regions.
   2. Desiccant pouch.
   3 Sample applicator.
B. Sample running buffer.
C. Package insert.

OPTIONAL MATERIAL REQUIRED

Stopwatch and Micro pipette.

STORAGE AND STABILITY

The sealed pouches in the test kit and the kit components may be stored between 4-30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE

1. For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE.
2. Do not use beyond expiry date.
3. Read the instructions carefully before performing the test.
4. Handle all specimens as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.
6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79- 9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

1. INSIGHT-RF uses human serum as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 1 week.
4. Refrigerated specimens must be brought to room temperature prior to testing.
5. Repeated freezing and thawing of the specimen should be avoided.
6. Do not use viscous/turbid, lipaemic, hemolysed, clotted and contaminated serum specimens.
8. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

TESTING PROCEDURE

1. Bring the kit components of INSIGHT-RF to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample applicator.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. Once opened, the device must be used immediately.
5. Label the device with specimen identity.
6. Place the testing device on a flat horizontal surface.
7. Using calibrated pipette, pipette out 500µl of sample running buffer and dispense into a test tube. Then pipette out 5µl of specimen and dispense into test tube (1:100 dilution), mix well. This is the test specimen.
8. Dispense 2 drops of the test specimen into the specimen port (S).
9. Start the stopwatch. Read the results within 5 minutes. Do not interpret the results beyond 8 minutes.

INTERPRETATION OF RESULTS

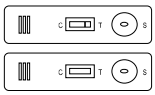
Negative Result:

The appearance of one pink/ purple coloured band at the Control Region (C) indicates absence of RF in the specimen.

Positive Result:

The appearance of two pink/purple coloured bands at the Control Region (C) and Test Region (T) indicates that the specimen contains detectable levels of RF.

Invalid Result:



The test result is invalid if no band appears on the device. The test should be considered invalid if only the test band appears and no control band appears. In such cases, verify the test procedure and repeat the test with a new INSIGHT RF device.

REMARKS

1. Markedly lipemic, hemolysed and contaminated serum samples could produce non-specific results.
2. Use of plasma rather than serum can lead to false positive results.
3. Most positive & negative results develop within 5 minutes. Do not interpret the results beyond 8 minutes.
4. Rheumatoid factors are not exclusively found in rheumatoid arthritis but sometimes in syphilis, systemic lupus erythematosus, hepatitis, hypergammaglobulinemia also.
5. It is recommended that results of the test should be correlated with clinical findings to arrive at the final diagnosis.

PERFORMANCE CHARACTERISTICS

The sensitivity of INSIGHT RF is 10 IU/ml.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Amy M. Wasserman et.al., Diagnosis and Management of Rheumatoid Arthritis, American Family Physician, Vol.84, No.11, Dec 1, 2011, pgs 1245-1252.
2. Clinical Laboratory Diagnostics Edited by Lothar Thomas, M.D., 1st Ed., 1998, TH-Books Verlagsgesellschaft mbH, Frankfurt, Germany, pgs 700-706.
3. Data on file: Tulip Diagnostics (P) Ltd.

Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

REGISTERED OFFICE: GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH, ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202, INDIA.

MANUFACTURING UNIT: PLOT NOS. 92/96, PHASE II C, VERNA IND. EST., VERNA, GOA-403 722, INDIA.

Website: www.tulipgroup.com

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